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APPLICATION NO.	FILING DATE	FIRST NAMED INV	ENTOR		ATTORNEY DOCKET NO.
09/045,73	34 03/20/98	LUCIANO		J	2000SD
-		QM12/0908	7	·	EXAMINER
SHARON L DAY 9 PLEASANT STREET				WINA	AKUR, E PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No. **09/045,734**

Applicant(s)

Luciano

Office Action Summary Examiner

Eric Winakur

Group Art Unit 3736



Responsive to communication(s) filed on Jul 23, 1999	·				
This action is FINAL .					
Since this application is in condition for allowance except for form in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.E.	D. 11; 453 O.G. 213.				
A shortened statutory period for response to this action is set to expision set to expision set to expanding the mailing date of this communication. Failure to reapplication to become abandoned. (35 U.S.C. § 133). Extensions of CFR 1.136(a).	spond within the period for response will cause the				
Disposition of Claims					
X Claim(s) 1-16, 36-38, 42, 44, and 60-75	is/are pending in the application.				
Of the above, claim(s)	is/are withdrawn from consideration.				
☐ Claim(s)					
	is/are rejected.				
Claim(s)					
☐ Claims are subject to restriction or election requirement.					
Application Papers					
See the attached Notice of Draftsperson's Patent Drawing Re	view, PTO-948.				
The drawing(s) filed on is/are objected t					
☐ The proposed drawing correction, filed on	isapproveddisapproved.				
☐ The specification is objected to by the Examiner.					
☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. § 119	,				
Acknowledgement is made of a claim for foreign priority under					
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the	e priority documents have been				
received.					
received in Application No. (Series Code/Serial Number					
received in this national stage application from the Inte	mational buleau (FC) nule 17.2(d)).				
*Certified copies not received: Acknowledgement is made of a claim for domestic priority ur	nder 35 U.S.C. § 119(e).				
Attachment(s)					
☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s).	. 3, 4				
☐ Interview Summary, PTO-413					
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948					
☐ Notice of Informal Patent Application, PTO-152					
SEE OFFICE ACTION ON THE	FOLLOWING PAGES				

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 - 16, 36 - 38, 42, 44, and 60 - 75 are rejected under 35 U.S.C. 112, second 2. paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 1 and 60, it appears that the term "of" (line 2) should read "for"; it is unclear how the method of step (a) relates to the other steps. With regard to claims 7 and 66, it is unclear what Applicant intends to set forth by the phrase "symptom severities". With regard to claims 9 and 68, it is unclear what Applicant intends to set forth by the phrase "response influence". With regard to claims 11, 12, 70, and 71, it is unclear whether Applicant intends to set forth a Markush group or some other relationship between the elements. With regard to claims 13 and 72, it is unclear what Applicant intends to set forth. With regard to claims 15 and 74, it is unclear whether step (b) is meant to merely claim development of a model, or if it also meant to include its evaluation as well; with regard to step (e), it is unclear how "monitoring" can "provide an updated outcome prediction" as set forth in the claims. With regard to claim 37, Applicant is requested to use numbers instead of letters to set forth the steps, as letters have already been used to set forth steps (a) - (g); it is unclear what Applicant intends to set forth in step (a), as a difference requires two values, and Applicant only appears to refer to one - the profile; it is unclear why Applicant sets forth separate steps (b) and (c), as they appear to relate to a single step of comparing the difference with a range to determine if the difference is within or outside of the

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range - for any given circumstance only one can be true at any time. With regard to claim 42, it is unclear how the claimed subject matter relates to the steps of the base claim.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 1 16, 36 38, 42, 44, and 60 75 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chaper 4 of the Luciano dissertation.
- 5. Claims 1, 8, 9, 13, 60, 64, 65, 67, 68, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker et al. in "Predicting Improvement in Patients ...". Parker et al. discuss results of a study of patients with non-endogenous depression which includes defining baseline values and performing analyses to allow prediction of outcome in patients receiving psychiatric assessment and therapy (see Results and Discussion sections in particular).
- 6. Claims 15, 16, 36 38, 42, 44, 74, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by the method used by a doctor in treating patients. Applicant appears to merely claim the steps used by a doctor in diagnosing and treating a patient, as a doctor will observe a patient's symptoms and test results (when needed), determine appropriate treatment options and form expectations regarding the patient's recovery (from previous experience), determine a most appropriate treatment and provide the patient with instructions, prescriptions, etc. to carry out the

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treatment, monitor the patient's progress, and make changes to the treatment regime depending upon the monitored progress.

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 2, 11, 12, 61, 70, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. as applied to claims 1, 5, 6, 8, 9, 13, 60, 64, 65, 67, 68, and 72. With regard to claims 2 and 61, although Parker et al. do not teach the particular manner in which their processing is implemented, it would have been obvious to one of ordinary skill in the art to implement the procedure on a computer since this would allow rapid evaluation of data. With regard to claims 11, 12, 70, and 71, Parker et al. do not teach that the specific factors set forth in the claims are included in their evaluation. Without a showing of unexpected results or criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to implement the procedure with the factors set forth in the claims, since it has generally been held to be within the skill level of the art to choose factors to optimize a procedure.
- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Beekman et al. discuss other studies regarding prediction of treatment and recovery of depression. Brill teaches an apparatus for measuring psychotherapy outcomes.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Winakur whose telephone number is (703) 308 - 3940. The examiner can normally be reached on Monday - Thursday from 7:30 AM to 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cary O'Connor, can be reached on (703) 308-2701. The fax phone number for this group is (703) 308 - 0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 - 0858.

Eric F. Winakur Art Unit 3736 August 30, 1999 5.12

Attachment	

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.